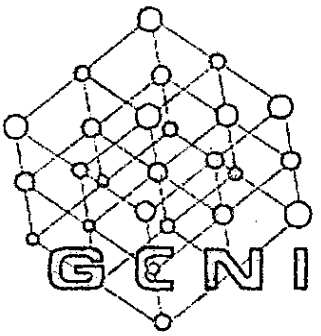

JUN 2 1 2013

TRADITIONAL 510 K SUMMARY

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510(k) Summary K123158

Submitter's name:	Ion Genius, Inc. / Ion Magnum LTD / UV Innovations Ltd
Address:	Corporate Headquarters and Shipping Address 1833 Kalakaua Ave Suite #905 Honolulu, HI 96815 Manufacturing Facility UV Innovations Ltd BIC 1 Innova Park Mollison Ave, Enfield, Middlesex, EN3 7XU, UK
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Date of Summary	

Is re-submitted:	June, 2013
FDA Establishment Registration No:	3003588228 (Ion Genius Inc)
Proprietary Name:	Ion Magnum Genius
Regulation Description:	Powered Muscle Stimulator for Muscle Conditioning
Panel Code	89
Product Code:	NGX
Submission Type	510(k)
Regulation Number	890.5850
Device Class	II
Trade Name:	ION MAGNUM GENIUS
Common Name:	Powered Muscle Stimulator for Muscle Conditioning
Classification Name:	Stimulator, muscle, powered, for muscle conditioning
Distributed by:	Ion Genius, INC / Ion Magnum LTD / UV Innovations LTD Corporate Headquarters and Shipping Address: 1833 Kalakaua #905 Honolulu, HI 96815 Tel: 866-25-YOUNG tel:808-395-0656 Fax: 877-26-YOUNG

PREDICATE:
Legally Marketed Devices

1.. Compex Sport
Compex, S.A.
Regulation No 890.5850
K 011880
Stimulator, muscle, powered, for muscle conditioning
Product Code: NGX

Action Taken to Comply with the requirements of section 514 of the act, regarding compliance with applicable performance standards in accordance with 21 CFR 807.87 (d)	Yes. A new improvement in the device design to enhance the device safety was the additional insulation of wires and other components near the chassis which is connected to the ground and the increase of the gap between wires and all other components and chassis to 9 milimeters. This new design significantly reduces the risk that the

	connections could be shorted to the ground. Manufacturing facility has been awarded ISO 13485: 2003 for the manufacture and sales of muscle stimulators 2011- 2014. There are extensive Bench tests prior to each Ion Magnum being released by the manufacturing facility with the pass sticker and the date that it passed next to the serial number of the device

Device Description:

Ion Magnum Genius is a muscle stimulator with six ports and one output that is the same for all ports. The unit is designed for healthy men & women to provide muscle conditioning. Ion Magnum Genius stimulator provides selections of different programs through manual adjustment of the three different frequencies of the device, 90 Hz, 100 Hz and 120 Hz which are within the same range as the predicate that offer a range from 1-120 Hz. The setting that the frequency button is turned shows which frequency the device is set on. The device delivers a voltage of 50 volts at 500 Ohms load and 100ma just like the predicate. It delivers a voltage of 200 volts at 10K Ohms just like the predicate. The Ion Magnum maximum output current is 100 ma which is equivalent to the maximum output current of the predicate. The Ion Magnum has a maximum output current of 200 volts which is equivalent to the maximum output current of the predicate. The device primarily treats abdominal muscles (ABS). LCD shows the balance treatment time. The output signal is biphasic, rectangular and based on a voltage and current regulated technology. The unit is easy and simple to use. Ion Magnum is suitable for use by all healthy adults. However as with other muscle stimulators some care is needed when using the Ion Magnum Genius (see contraindications and warnings in manual)

NOTE 1: All channel;s outputs are isolated from each other. They have their own transformers and amplifiers which are independent from neighboring channels or outputs. The only common thing between the outputs is their connectors to the power supply, the start button, the programs button and the pulse button.
There is a transformer that translates energy received from the mains into micro currents. Hence there is an insulation of mains from circuitry. From Circuitry to output there is also insulation through the transformer. Therefore there is a double separation between mains and the human body.

This unit contains 24 self-adhesive electrodes that already have 510K clearance (K970426)

The Ion Magnum power source is 110V – 240 V AC Mains, 50-60Hz The patient leakage current is 0.07 microamps under both the normal and fault conditions.. A new improvement in the device design was made in 2012 in order enhance the device safety which entailed the additional insulation of wires and other components near the chassis. The increase of the gap between wires and all other components and chassis is now increased at least 9 millimeters. This new design safety significantly reduces the risk that the connections could be shorted to the ground.

Channels are synchronous and are isolated by separate transformers the way the channels or the predicate are synchronous and isolated by separate transformers. Ion Magnum Genius has an automatic overload trip, just like the predicate but not an automatic no load trip just like the predicate that do not have a no load trip, therefore in terms of the overload trip features the Ion Magnum Genius and the predicate are substantially equivalent. The Ion Magnum Genius is also equivalent to the predicate in that it has an automatic shut off and patient override control for additional safety. Indicator displays include on and off status just like it does in the predicate. Ion Magnum Genius is an IEC 1 device, IEC 60417-5333, type BF applied part device.

Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		

Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?	X	
Is the device implanted?		X

Intended Use

Ion Magnum Genius is intended for muscle conditioning to stimulate healthy muscles. The Ion Magnum Genius is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Ion Magnum Genius programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The Ion Magnum Genius is only offered under prescription given by a physician licensed in the state in which he or she practices.

COMPARISON OF INDICATIONS FOR USE OF ION MAGNUM GENIUS AND PREDICATE

Ion Magnum Genius is intended for muscle conditioning to stimulate healthy muscles. The Ion Magnum Genius is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Ion Magnum Genius programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The Ion Magnum Genius is only offered under prescription given by a physician licensed in the state in which he or she practices.	Compex Sport" [K011 80] is intended for muscle conditioning to stimulate healthy muscles in order to improve or facilitate muscle performance. "Compex® Sport" is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the "Compex® Sport" training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.

Substantial Equivalence based on the Indicatins of Use Statement: When compared to the predicated device, Compex® Sport K011880 the Ion Magnum Genius has the same intended use. Therefore, the Ion Magnum Genius is substantially equivalent to the predicate marketed device Compex® Sport K011880.

COMPARISON OF DEVICE DESCRIPTION, SAFETY AND EFFECTIVENESS OF ION MAGNUM GENIUS TO PREDICATE DEVICES:

Ion Magnum Genius is a Muscle stimulator with six independent channels which electrical current can be regulated individually Biphasic rectangular impulses with electrical mean equal to zero. Maximum output current is 100 mA and maximum voltage output is 200 volts. The device gives 50V output at 500 Ohms overload and 200 volts at 10K Ohms overload. Maximum quantity of electricity per channel:40 µC Impulse width: 400 to 500 µsecs. The three Ion Magnum Genius frequencies, 90 Hz, 100 and 120Hz are within the same range as the predicate. The electrical pulses generated by the Ion Magnum Genius are transmitted to the muscles via self-adhesive electrodes, Axelgaard type electrodes electrodes (510K K970426) The electrodes are equivalent to those used by the predicate.	**Compex Sport" (K01180)** has: Four independent channels which electrical current can be regulated individually. Biphasic rectangular impulses with electrical mean equal to zero Maximum output current is 100 mA and maximum voltage output is 200 volts. The device gives 50V output at 500 Ohms overload and 200 volts at 10K Ohms overload. Maximum quantity of electricity per channel:40 µC impulse width: 200 or 400 µS. Range of pulse frequency: 1-120 Hz The electrical pulses generated by *"Compex® Sport"* are transmitted to the muscles via self-adhesive electrodes.

Other equivalence aspects between Ion Magnum Genius and the Predicate

Other equivalence aspects between Ion Magnum Genius and the Predicate	1. Ion Magnum Genius and the predicate devices are identical in terms of the thermal safety (there is no thermal energy for Ion Magnum Genius or the predicate) 2. The chemical safety is equivalent (since this is applicable to neither the Ion Magnum Genius nor the predicate) 3. Sterility is equivalent (since neither the Ion Magnum Genius nor the predicate require sterilization or are supplied sterile.) 4. The Ion Magnum Genius uses disposable pads that do not need sterilization that are equivalent to the pads of the predicate which also do not need sterilization because they are disposable. 5. Biocompatibility of the Ion Magnum disposable pads is equivalent to those of the predicate. Biocompatibility is performed by the company from which these disposable pads are purchased (Axelgaard). Ion Magnum uses disposable pads item no: SN2020 which are square 2" x 2" (5cm x 5cm) which have a 510K number K970426 and comply to ISO10993-5 Biological Evaluation of Medical Devices part 5 Test for in vitro cytotoxicity & ISO10993-10. The are made by Axelgaard Manufacturing Co. LtD, 520 Industrial Way Fallbrook California 92028, USA which has a Certificate of Registration Quality Management System - ISO 13485:2003 and holds certificate no FM 40363 and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope: The design and development, manufacture and

	distribution of hydrogel and non-invasive electrodes: Effective date 03/11/2012 – Expiry Date: 03/12/2015.).. 6. The cables carrying the impulses to the pads and the connectors are both designed to insulate the client and operator from inadvertent contact with the relatively weak electrical impulses. Should the connectors be dislodged in use, for instance, by the client changing position during treatment, the insulation will ensure no direct contact with the skin will take place. The Ion Magnum cables remain screwed on and attached to the device as are the cables of the predicate devices.

OUTPUT SPECIFICATIONS COMPARING ION MAGNUM GENIUS WITH THE PREDICATE DEVICES

	ION MAGNUM GENIUS	Compex Sport K011880
Waveform	Biphasic	Biphasic
Synchronous or alternating channels	synchronous	synchronous
Dimension of Device	15.5 inches length 8,5 height 7.5 width	Length: 142 mm Widthg 99mm Height 36mm
Weight of the Device Weight of Accessories	8 pounds 4.7 pounds	350 g 95 g
Indicator Display Low Battery Voltage Current Level	Yes N/A Yes	Yes Yes Yes
Shape	Rectangular	Rectangular
Max Output Voltage	50V @ 500 Ω	50V
	200 V @10k Ω	200 V +/- 10
Net Charge	0.01 amperes at 500 Ohms 0.004 Amperes at 2K ohms 0.0025 Amperes at 10K Ohms	
Max Output Current	100 ma at 500 Ohms	100 ma at 500 Ohms

Frequency (Hz) for Muscle Conditioning	90 Hz 100 Hz 120Hz	1-120 Hz
Pulse Duration	416 - 500 µsec	200 to 400 µsec
Pulse Width	416 - 500 µsec	200 to 400 µsec
Maximum Phase Charge	50 µC @ 500 Ω at 90 and 100 Hz 40 µC @ 500 Ω at 120 Hz	40 µC
Maximum Current Density (mA/cm2)	4 mA /cm2	4 mA/cm2
Maximum Power Density (W/Cm2)	0.0012 W/cm^2	0.038 W/cm^2.
Current or Voltage Driven	Current Driven Voltage	Current Driven Voltage
Symmetrical Phases of Waveform	Yes	Yes
Regulated Current/ voltage	Regulated Voltage and Regulated Current.	Constant Current Regulator / regulated current
Method of Channel Isolation	Channels are isolated by separated transformers	Channels are isolated by separated transformers
Self Adhesive Electrodes Axelgaard Tyoe	identical	Identical

Current Leakage	0.07 µA	>100 microamps

DIFFERENCES BETWEEN ION MAGNUM AND PREDICATE:.

1. The Ion Magnum Genius has 6 channels while the Compex Sport has 4 channels. However, the exact same output comes out of all Ion Genius channels. Risk assessment testing has indicated that output coming out of six channels simultaneously is equally safe as output coming out of four channels simultaneously.

2. The Ion Magnum Genius does not have software, a microcomputer or firmware, while the predicate device is controlled by a microcomputer. However this difference does neither affect the indications of use or the safety and effectiveness of the Ion Magnum Genius.

3. THE ION MAGNUM GENIUS IS ONLY OFFERED UNDER PERSCRIPTION AND IT IS ONLY OFFERED AS A BUSINESS TO BUSINESS DEVICE SOLD ONLY TO PHYSICIANS WHICH MEANS THAT THE ION MAGNUM GENIUS WILL BE NEVER BE USED BY AN INDIVIDUAL AT HOME. ADMINISTRATION OF THE ION MAGNUM TREATMENT WILL ALWAYS BE BY A TRAINED PHYSICIAN AND THEREFORE A PATIENT RECEIVING A TREATMENT WITH THE ION MAGNUM TREATMENT WILL ALWAYS HAVE THE ADVANTAGE OF THE PHYSICIAN'S CLINICAL JUDGEMENT. A PHYCISIAN WILL ALSO BE AVAILABLE FOR CONSULTATION WITH ANYTHING REGARDING THE ION MAGNUM AND OVERALL ADDITIONAL SAFETY.

4. The Ion Magnum Genius has a different weight than the predicate. However this difference does neither affect the indications of use or the safety and effectiveness of the Ion Magnum Genius.

SUBSTANTIAL EQUIVALENCE DISCUSSION

1. Substantial Equivalence on the basis of Indication for Use

The Ion Magnum and the predicate devices have the same intended use and equivalent indications, and principles of operation that includes the delivery of small amount of electrical stimulation to healthy skeletal muscles for conditioning of the muscles.

2. **Substantial Equivalence on the basis of Technological characteristics:**

The Ion Magnum Genius and the predicate have a number of similarities in terms of their technological characteristics cited below:

1. Biphasic Rectangular Waveform
2. Synchronous channels
3. Maximul output voltage
4. Maximum output current
5. range of frequencies
6. Pulse Duration
7. Pulse width
8. Maximum Phase Charge
9. Maximum Current Density

10. Channels' method of isolation by separate transformers
11. Identical Electrodes
12. Similar current leakage

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 21, 2013

Ion Genius
c/o Xanya Sofra-Weiss, Ph.D.
Director of Research and Training
7192 Kalanianole Hwy #D-204A
Honolulu, HI 96821

Re: K123158
Trade/Device Name: Ion Magnum Genius
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: June, 2013
Received: June 7, 2013

Dear Dr. Sofra-Weiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours.

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123158

Device Name: Ion Magnum Genius

Indications For Use:

Ion Magnum Genius is intended for muscle conditioning to stimulate healthy muscles. The Ion Magnum Genius is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Ion Magnum Genius programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The Ion Magnum Genius is only offered under prescription given by a physician licensed in the state in which he or she practices.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123158